OCT 3 0 2003

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	Nikkiso Co., LTD Mr. Noboru Tsuchida Manager of Quality Control Medical Devices Factor 498-1, Shizutani, Haibara-cho, Haibara-gun, Shizuoka 421-496 Japan Phone number: +81-548-22-5808 Medical Equipment Unit
Contact Person:	Harry Alcorn, Jr. PharmD. Chief Operating Officer DaVita Clinical Research (TRRI) 825 South 8th Street Minneapolis, MN 55404 Telephone: 612-347-6367 Fax: 612-677-3243 E-mail: halcorn@Davita.com
Date Prepared:	October 20, 2003
Trade Name:	The DBB-05 Hemodialysis Delivery System
Classification Name and Number:	Class II High Permeability Hemodialyzer 21 CFR 867.5860
Product Code:	KDI
Predicate Device(s):	The subject device is substantially equivalent to the Fresenius Hemodialysate System, model 2008H, (K994267) manufactured by Fresenius Medical Care North America.

Device Description:	The subject device is composed of a hydraulic unit for the delivery of dialysate and extracorporeal blood circuitry. The permeate is heated and deaerated in the hydraulic section, which is then mixed with concentrate and fed into the dialyser through the dialysate fluid feeder. The closed balancing system assures the amount of dialysate infused corresponds to the amount of dialysate extracted. The interior pressure of the dialyser is controlled automatically by adjustment of the ultra filtration amount and UF rate by the dialyser. Heparinization of the external circulating blood can be done with the heparin pump either by continuous or one-shot injection before it is passed on to the dialyser. The subject device uses both acetate dialysis and bicarbonate dialysis. Using the various functions the device, the conductivity and UF profile can be programmed. In addition, the subject device incorporates all functions necessary for double-needle dialysis as well as single-needle dialysis treatment. The hydraulic unit is cleaned and disinfected using

	selectable cleaning programs and is equipped with the necessary protective systems for patient safety and correct operation.
Intended Use:	The DBB-05 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult and pediatric patients with acute or chronic renal failure. The DBB-05 is intended for hemodialysis performed in hospitals and dialysis clinics by a qualified operator.
Functional and Safety Testing:	Functional and safety testing of the DBB-05 Hemodialysis Delivery System consisted of performance tests that include electrical safety, failure simulation and software tests. Examination of device function was performed under conditions similar to those found in normal usage to ensure conformance with product specifications. The result of the testing was successful. The device performed as designed and met, or exceeded, all product specifications.
Conclusion:	The DBB-05 Hemodialysis Delivery System, manufactured by Nikkiso Co., LTD, is substantially equivalent to Fresenius Hemodialysate System, model 2008H, (K994267) manufactured by Fresenius Medical Care North America. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and other device features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Nikkiso Co., LTD
c/o Harry Alcorn, Jr., PharmD.
Chief Operating Officer
DaVita Clinical Research (TRRI)
825 South 8th Street
MINNEAPOLIS MN 55404

Re: K023509
Trade/Device Name: DBB-05 Hemodialysis Delivery System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 21, 2003
Received: August 25, 2003

Dear Dr. Alcorn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023509

Indications for Use Page

Device Name: The DBB-05 Hemodialysis Delivery System

Indications for Use:

The DBB-05 Hemodialysis Delivery System is indicated for hemodialysis prescribed by physicians for adult and pediatric patients with acute or chronic renal failure. The DBB-05 is intended for hemodialysis performed in hospitals and dialysis clinics by a qualified operator.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023509

Prescription Use ✓
(Per 21 CFR 801.109)